Light-intensity Physical Activity and Arterial Stiffness in Type 2 Diabetes

Published: 22-12-2016
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To evaluate the effect of a LiPA intervention on arterial stiffness in individuals with T2D.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON55739

Source
ToetsingOnline

Brief title
LiPAT

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes, hardening of the arteries

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: European Foundation for the Study of Diabetes (EFSD)

Intervention

Keyword: arterial stiffness, randomized controlled trial, sedentary behaviour, type 2

diabetes

Outcome measures

Primary outcome

The primary outcome is pulse-wave velocity and carotid distensibility which will be determined with the use of applanation tonometry and arterial ultrasound. The effect of the intervention on the primary outcome PWV at month 6 will be analysed.

Secondary outcome

Secondary outcomes include the amount of physical activity and sedentary behaviour, metabolic risk factors (fasting glucose, fasting insulin, HbA1c, lipid profile, creatinine, albumin and biomarkers of endothelial dysfunction (vWF, s-VCAM-1, sE-selectin, sTM, SICAM-1) and low-grade inflammation(CRP, SAA, IL-6, TNF-alfa, IL-8) and blood pressure); body composition (weight, fat mass); quality of life; and depressive symptoms.

Study description

Background summary

In type 2 diabetes (T2D), physical activity is an important modifiable risk factor of cardiovascular disease (CVD) and increased physical activity has been shown to positively impact cardiovascular health. Unfortunately (long-term) compliance to exercise programs in patients with T2D is poor. Light-intensity physical activity ((LiPA); i.e., walking slowly, household activities or taking a flight of stairs) is also associated with a decreased CVD risk and can be more easily incorporated into daily life.

Study objective

To evaluate the effect of a LiPA intervention on arterial stiffness in

individuals with T2D.

Study design

This study is a single-blinded randomized controlled trial. The duration of the study is 12 months; a 6-month intervention with a 6 month follow-up period.

Intervention

The intervention group will receive 4 workshops focussing on strategies to increase LiPA by reducing sedentary time. Participants in the intervention group will receive a feedback physical activity monitor worn on the wrist, data will be synchronized with a mobile phone app. The activity monitor will give real-time feedback on activity levels and will be used to set activity goals. Participants in the intervention group are encouraged to decrease their sedentary time with 10%. Participant in the control group will also receive 4 workshops focused on healthy lifestyle and do not receive an activity monitor.

Study burden and risks

Study measurements of all participants will take place at baseline, month 3, month 6, and month 12 at the Maastricht UMC+. For the LiPA intervention only non-invasive low risk study procedures will be performed and the risk for any adverse events due to the different study procedures low. The burden of the intervention for participants is low since LiPA can be easily incorporated in daily life.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- 40-70 years old
- having type 2 diabetes
- BMI 20-35 kg/m2
- having a sedentary lifestyle (i.e., self-reported moderate-to-vigorous physical activity < 150 minutes per week)
- willingness to undergo randomization
- being in the possession of personally owned smart phone

Exclusion criteria

- not being able to walk for 15 minutes for any (medical) reason
- currently engaged in an (medical) exercise program
- plan to move out of the study area in the next 12 months
- (digital) illiteracy or being unable to read Dutch
- a history of any cardiovascular event (including stroke) three months prior to possible inclusion
- a history of signs or symptoms of ischemic heart disease and(or) heart failure three months prior to possible inclusion
- a history or signs or symptoms of peripheral arterial disease three months prior to possible inclusion
- a history or signs or symptoms of severe diabetic neuropathy or diabetic foot ulcers three months prior to possible inclusion
- a history of sign or symptoms of severe diabetic retinopathy three months prior to possible inclusion
- a history or sign or symptoms of severe osteoarthritis or severe joint complaints three months prior to possible inclusion
- a history or signs or symptoms of COPD (eligible are those participants with

a COPD Gold classification <= I)
- uncontrolled diabetes (i.e., uncontrolled hypo- or hyperglycaemia)
- uncontrolled hypertension (i.e., systolic / diastolic blood pressure >= 180 / 95 mmHg)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-11-2018
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO Date:	22-12-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	20-12-2018
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	05-06-2019

Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL57173.068.16